

Claims:

1. A lateral flow quantitative assay method comprising:

5 applying a liquid sample that is expected to contain an analyte to one end of a chromatography medium;

 migrating the liquid sample through the chromatography medium to react the analyte with a
10 labeled detector adsorbed on a section located at a predetermined distance from the sample application site in a sample developed direction, thereby forming an analyte/labeled detector conjugate;

 migrating the analyte/labeled detector conjugate
15 through the chromatography medium to react the analyte/labeled detector conjugate with an unlabeled captor that is identical to or different from the detector and immobilized on a viewing window defined around a middle portion of the chromatography medium,
20 thereby forming a labeled detector/analyte/unlabeled captor triple conjugate in which the analyte is captured between the labeled detector and the unlabeled captor in a sandwich-like fashion; and

measuring an amount of the triple conjugate to quantify the analyte in the liquid sample,

wherein the method is characterized in that:

(a) the labeled detector is labeled with a
5 fluorescent substance and reacts with the analyte in the liquid sample to form the fluorescently-labeled detector/analyte conjugate;

(b) the unlabeled captor is dispensed in lines within a viewing window on the chromatography medium and
10 reacts with the fluorescently-labeled detector/analyte conjugate that has been migrated along the chromatography medium to form the fluorescently-labeled detector/analyte/unlabeled captor triple conjugate;

(c) a reference detector, which is different from
15 the detector and the captor and labeled with a fluorescent material identical to that used in labeling the detector and reacts with a reference material in the liquid sample, is adsorbed on the section of the chromatography medium where the fluorescently-labeled
20 detector is adsorbed, and an unlabeled reference captor that reacts with the fluorescently-labeled reference detector is dispensed and immobilized in double reference lines in front of the viewing window on the chromatography medium to provide a reference conjugate

of fluorescently-labeled reference detector/reference material/unlabeled reference captor as the liquid sample passes through the chromatography medium; and

(d) an amount of the analytes is determined by
5 passing a laser presented from a shape control lens for laser beam through an exciter filter, irradiating the filtered light to the epifluorescence medium containing the triple analyte conjugate and the reference conjugate, passing light reflected from the
10 epifluorescence medium through a collection lens to form parallel light, passing the parallel light through a fluorescent filter to remove scattered incident light and presenting only a pure fluorescence component to a condenser lens to focus the pure fluorescence component
15 to a center of a pinhole, removing light except for the parallel light at the pinhole, presenting the parallel light to an optical detector, transmitting the incident parallel light to a CPU via an analog digital converter (ADC), and comparing a fluorescence intensity of the
20 triple analyte conjugate with a reference fluorescence intensity of the reference conjugate to quantify the analyte.

2. The lateral flow quantitative assay method as set forth in claim 1, being characterized in that an Ag line with which Ag or a detector reacts is further immobilized in back of the viewing window to extend
5 signal detection range by calculating a signal variation of the Ag line.

3. The lateral flow quantitative assay method as set forth in claim 1, wherein the unlabeled reference
10 captor is mouse IgG.

4. The lateral flow quantitative assay method as set forth in claim 1, wherein the detector is used in a number of three to five, and the captor is selected from
15 among α -feto protein (AFP), carcinoembryonic antigen (CEA), CA15-3, CA19-9 and CA125 in an identical number to the number of the detector and dispensed and immobilized in identical lines to those of the captor within the viewing window, thereby allowing simultaneous
20 quantitative analysis of three to five analytes.

5. A lateral flow quantitative assay strip, comprising:
a backing;

a sample pad adhered to one end of the backing and to which a liquid sample is applied;

a conjugate releasing pad adhered to the backing in such a way that one end of the sample pad, close to
5 an opposite end of the backing, overlaps with an end of the conjugate releasing pad to which a labeled detector is releasably attached to react with an analyte in the liquid sample to form a conjugate;

a chromatography medium adhered to the backing in
10 such a way that one end of the medium overlaps with an end of the conjugate releasing pad, close to an opposite end of the backing, and on which a captor is immobilized, which is identical to or different from the detector and reacts with and captures a conjugate
15 released from the conjugate releasing pad as the sample develops to form a sandwich type conjugate; and

an absorption pad to absorb the sample developing along the chromatography medium and to absorb and remove unreacted labeled substances,

20 wherein the strip is characterized in that:

the detector releasably attached to the conjugate releasing pad is labeled with a fluorescent material;

a reference detector that is labeled with a fluorescent material identical to that used in labeling

the detector and reacts with a reference material in the liquid sample is further releasably attached to the conjugate releasing pad;

5 the captor is dispensed and immobilized in lines within a viewing window on the chromatography medium, and

an unlabeled reference captor that is different from the detector and the captor is dispensed and immobilized in double reference lines in front of the viewing window on the chromatography medium, to form a conjugate of fluorescently-labeled detector/analyte/unlabeled captor and a reference conjugate of fluorescently-labeled reference detector/reference material/unlabeled reference captor
10 as the liquid sample passes through the chromatography medium; and
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an amount of the analyte is determined by passing a laser presented from a laser beam shape control lens through an exciter filter, irradiating the filtered light to the epifluorescence medium containing the triple analyte conjugate and the reference conjugate,
20 passing light reflected from the epifluorescence medium through a collection lens to form parallel light, passing the parallel light through a fluorescent filter

to remove scattered incident light and presenting only a pure fluorescence component to a condenser lens to focus the pure fluorescence component to a center of a pinhole, removing light except for the parallel light at the pinhole, presenting the parallel light to an optical detector, transmitting the incident parallel light to a CPU via an analog digital converter (ADC), and comparing a fluorescence intensity of the triple analyte conjugate with a reference fluorescence intensity of the reference conjugate to quantify the analyte.

6. The lateral flow quantitative assay strip as set forth in claim 5, being characterized in that an Ag line with which Ag or a detector reacts is further dispensed and immobilized in back of the viewing window to extend signal detection range by calculating a signal variation of the Ag line.

7. The lateral flow quantitative assay strip as set forth in claim 5, wherein the unlabeled reference captor is mouse IgG.

8. The lateral flow quantitative assay strip as set forth in claim 5, wherein the detector is used in a

number of three to five, and the captor is selected from among α -feto protein (AFP), carcinoembryonic antigen (CEA), CA15-3, CA19-9 and CA125 in an identical number to the number of the detector and dispensed and
5 immobilized in identical lines to those of the captor within the viewing window, thereby allowing simultaneous quantitative analysis of three to five analytes..

9. A small scanner for quantitative analysis of
10 an analyte, which is integrated with a laser-induced epifluorescence detection device into a single body,

wherein the laser-induced epifluorescence detection device comprises:

- (i) a strip, comprising:
15 a backing;
a sample pad adhered to one end of the backing and to which a liquid sample is applied;
a conjugate releasing pad adhered to the backing in such a way that one end of the sample pad, close to
20 an opposite end of the backing, overlaps with an end of the conjugate releasing pad to which a labeled detector is releasably attached to react with an analyte in the liquid sample to form a conjugate;

a chromatography medium adhered to the backing in such a way that one end of the medium overlaps with an end of the conjugate releasing pad, close to an opposite end of the backing, and on which a captor is
5 immobilized, which is identical to or different from the detector and reacts with and captures a conjugate released from the conjugate releasing pad as the sample develops to form a sandwich type conjugate; and

an absorption pad to absorb the sample developing
10 along the chromatography medium and to absorb and remove unreacted labeled substances,

wherein the strip is characterized in that:

the detector releasably attached to the conjugate releasing pad is labeled with a fluorescent material;

15 a reference detector that is labeled with a fluorescent material identical to that used in labeling the detector and reacts with a reference material in the liquid sample is further releasably attached to the conjugate releasing pad;

20 the captor is dispensed and immobilized in lines within a viewing window on the chromatography medium; and

an unlabeled reference captor that is different from the detector and the captor is dispensed and

immobilized in double reference lines in front of the viewing window on the chromatography medium;

(ii) a cartridge to install therein the strip, the cartridge including a sample loading inlet and a window having a sloped wall surface, which are formed on a top plate of a cartridge housing; and

(iii) a laser, a shape control lens for laser beam, an exciter filter, a collection lens, a fluorescent filter, a condenser lens, a spatial filter, an optical detector, an analog digital converter (ADC) and a CPU,

wherein the components of the detection device are arranged in a structure such that a laser presented from a lens for control of shape of a laser beam of the laser is passed through an exciter filter, the filtered light is irradiated to an epifluorescence medium containing a conjugate of fluorescently-labeled detector/analyte/unlabeled captor and formed in the viewing window and a reference conjugate of fluorescently-labeled reference detector/reference material/unlabeled reference captor formed in the reference line as the liquid sample passes through the chromatography medium of the strip, light reflected from the epifluorescence medium is passed through a

collection lens to form parallel light, the parallel light is passed through a fluorescent filter to remove scattered incident light, only a pure fluorescence component is presented to a condenser lens to focus the
5 pure fluorescence component to a center of a pinhole, light except for the parallel light is removed at the pinhole, the parallel light is presented to an optical detector, and the incident parallel light is transmitted to CPU via an analog digital converter (ADC),

10 wherein the small scanner allows the detection device to determine an amount of the analyte in the sample by comparing a fluorescence intensity of the triple analyte conjugate with a reference fluorescence intensity of the reference conjugate.

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10. The small scanner as set forth in claim 9, wherein the unlabeled reference captor is mouse IgG.

11. The small scanner as set forth in claim 9,
20 wherein the detector is used in a number of three to five, and the captor is selected from among α -feto protein (AFP), carcinoembryonic antigen (CEA), CA15-3, CA19-9 and CA125 in an identical number to the number of the detector and dispensed and immobilized in identical

lines to those of the captor within the viewing window, thereby allowing simultaneous quantitative analysis of three to five analytes.

5 12. The small scanner as set forth in claim 9, wherein the window wall surface of the cartridge housing has a slope angle of 20° or less relative to the strip.

10 13. The small scanner as set forth in claim 9, being characterized in that an Ag line with which Ag or a detector reacts is further dispensed and immobilized in back of the viewing window to extend a signal detection range by calculating a signal variation of the Ag line.

15 14. The small scanner as set forth in claim 9, wherein the cartridge further includes a time reading window on the top plate of the cartridge housing, and a pH paper or an indicator attached to a protein is
20 attached onto the strip, to determine whether to start strip reading by the time reading window color by detecting change of the pH paper or the indicator when a sample is loaded through the sample loading inlet and contacts the absorption pad.

15. The small scanner as set forth in claim 9,
wherein the cartridge further includes a time reading
window on the top plate of the cartridge housing, and an
5 anti-detector ligand is further dispensed in a time
control line on a strip, to determine whether to start
strip reading by time reading window by measuring
intensities of fluorescence emitted from the detector
accumulated in the time control line by the laser-
10 induced epifluorescence detection device.

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